



Political Science and the FDA

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Political Science and the FDA

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Food and Drug Law
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I. Introduction

Politics has been characterized as the struggle for “who gets what, when, and how,”¹ and political science is the study of how that struggle is conducted and resolved. Since there is so much to “get” when it comes to the industries regulated by the Food and Drug Administration (“FDA”),² it is somewhat surprising that relatively little study of FDA has been undertaken by political scientists. In describing what political scientists can add to the study of regulatory policy apart from the contributions of economists, lawyers, sociologists, and journalists, renowned political scientist Morris Fiorina noted that while these other professionals typically study behavior undertaken within the constraints imposed by government officials, political scientists ask why the constraints are imposed in the first place and consider externally-imposed constraints as only one factor in determining why a government or a governmental unit behaves the way it does.³ This essay collects and analyzes the important political science works on FDA, with an eye both to serving as a springboard for future research on FDA decision-making and to drawing conclusions from extant research.

¹See, e.g., HAROLD D. LASSWELL, *POLITICS – WHO GETS WHAT, WHEN, HOW* (1958).

²FDA-regulated products account for twenty-five cents of every consumer dollar spent in the United States. See Food and Drug Administration, *About the U.S. Food and Drug Administration* (visited January 13, 2001) <<http://www.fda.gov/opacom/hpview.html>>.

³See Morris P. Fiorina, *Group Concentration and the Delegation of Legislative Authority*, in *REGULATORY POLICY AND THE SOCIAL SCIENCES* 173, 173-74 (Roger G. Noll ed., 1985).

Both of these goals require a brief discussion of “explanatory frameworks;” the future researcher will appreciate a conceptual categorization of the political science literature, and any analysis of existing studies should at least make explicit which framework those studies implicitly adopt. Social scientists have devised many sets of explanatory frameworks for analyzing government decision-making, and a good beginning reference point is Theodore R. Marmor’s *Commentary, or the Notes and Asides of an FDA Amateur and Professional Political Scientist Specializing in Battles over the Modern Welfare State*.⁴ Marmor defines explanatory frameworks (or “conceptual models”) as the “intellectual orientation and conceptual categories the analyst brings to complex political and organizational phenomena: how problems are framed, what unit of analysis is presumed, what focal notions, and what patterns of inference,”⁵ and he rightly criticizes other writers on FDA for failing to be precise about their own explanatory frameworks.

Basing his discussion on a well-known work by Graham Allison,⁶ Marmor describes three such frameworks: the “rational (or unitary) actor model,” the “organizational process model,” and the “bureaucratic politics model.”⁷ The *rational actor model*, as its name might imply, views FDA as merely a representative of the government.⁸ Under this model, when FDA takes some action or stance, it does so because the government as a whole has made a strategic choice that this action or stance was the best under the circumstances. Particularly relevant to this sort of analysis are the policy reasons behind certain regulations, enforcement mechanisms, and approval patterns. The *organizational process model* directs its attention to the laws and habits that form the processes a unit or sub-unit of government (here, FDA) follows. While the rational

⁴82 VA. L. REV. 1867 (1996).

⁵*Id.* at 1870.

⁶GRAHAM T. ALLISON, ESSENCE OF DECISION: EXPLAINING THE CUBAN MISSILE CRISIS (1971).

⁷Marmor, *supra* note 4, at 1870-71. It should be emphasized that this set of explanatory frameworks is not the only set that has been formulated, but it is one of the best known.

⁸This idea has also been expressed by the “principle-agent model” of bureaucratic functioning. For a survey of the literature adopting this view, see B. DAN WOOD & RICHARD W. WATERMAN, BUREAUCRATIC DYNAMICS 22-26 (1994).

actor model might explain an FDA regulation by focusing on the reasons why such a regulation might objectively be a good idea, the organizational process model pays more attention to “what reasons made sense to a particular organization with its distinctive habits, routine channels of information, and crucial internal history.”⁹ Finally, the *bureaucratic politics model* emphasizes the interaction of individual actors in “bargaining games.”¹⁰ This model explains a given FDA action “as the momentary resultant (or vector) of individuals, interests, and interactions.”¹¹

Before the political science literature is discussed using these explanatory frameworks, a few cautionary notes are warranted. First, the frameworks are not mutually exclusive. A scholar can analyze FDA decision-making using more than one. This is because the frameworks are not competing explanations of how FDA works; rather, they are simply different ways of sifting through a nearly infinite pool of data to determine what is important. Therefore, this essay can at most suggest which framework is the most useful vis-à-vis FDA; it cannot say which is “right.” Second, all conceptual models blur at the edges. Political scientists are sometimes not explicit about what they believe is important in the picture they present, and they include different sorts of facts that are primary for different frameworks. Moreover, even if they attempted to confine their descriptions to a single model, the models themselves would often not oblige. For example, historical information, depending on its presentation, can suggest either a unitary government view (as it has been categorized here) or an organizational habits and routines view; likewise, information about FDA’s incentives can be relevant both to the latter view and to the bureaucratic politics model. Finally, a few works fit so awkwardly into any one of these models that they are categorized separately below.

⁹*Id.* at 1871.

¹⁰*Id.*

¹¹*Id.* at 1872.

II. The Rational Actor Model

Political science works that rely heavily on history to explain why certain decisions were made about how to regulate food or drugs, and why the system is as it is now, generally assume a monolithic decision-maker – the government – responding to outside events and reacting as any rational actor put in the government’s place would act. Thus in her book *Strategic Uses of Public Policy*, Donna Wood describes the “public outrage” hypothesis of FDA regulation.¹² This hypothesis explains food and drug law as a response to various events that bring problems to the government’s attention. For example, Wood evaluates the impact of Upton Sinclair’s *The Jungle* (1905): “Theodore Roosevelt... sent his own blue-ribbon investigatory team to confirm Sinclair’s fictional account, and the Meat Inspection Act raced through Congress and was signed by the President on June 30, 1906.”¹³ Likewise, the 1938 Food, Drug, and Cosmetic Act (“FDCA”) was a governmental response to the Elixir Sulfanilamide deaths, and the 1962 amendments to that act were passed because of the phocomelia-causing drug thalidomide.¹⁴ Political economist Robert Higgs runs through the same crisis-response list, although he calls this process “punctuated politics” instead of the “public outrage” hypothesis.¹⁵

Peter Temin’s *Taking Your Medicine*¹⁶ is a more general history than Wood’s, and it is unique in the way he uses the history of food and drug regulation in conjunction with a psycho-social model of politics to understand FDA decision-making. In his model Temin posits three decision-making methods.¹⁷ First, the

¹²DONNA J. WOOD, *STRATEGIC USES OF PUBLIC POLICY: BUSINESS AND GOVERNMENT IN THE PROGRESSIVE ERA* 6-9 (1986). Despite this book’s broad title, the entire work is on the regulation of *food and drugs* in the progressive era.

¹³*Id.* at 6. Wood questions, however, the commonly-held notion that the Pure Food Act of 1906 (although it became law the same day) was also spurred on by *The Jungle*. She advances other reasons (consistent with the rational actor model) for its passage. *Id.* at 6-7.

¹⁴*Id.* at 7.

¹⁵Robert Higgs, *Introduction to HAZARDOUS TO OUR HEALTH? FDA REGULATION OF HEALTH CARE PRODUCTS* 1, 2-3 (Robert Higgs ed., 1995).

¹⁶PETER TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* (1980).

¹⁷*Id.* at 163-66.

“instrumental” method is characterized by the definition of goals and the rational assessment of various strategies to meet those goals. The “customary” method, on the other hand, uses habit or tradition as the guidepost. Finally, the “command” method describes the situation where the decision-maker abdicates the decision to another entity. Furthermore, the model used by the decision-maker changes depending on the context. To use Temin’s own example, a perfectly healthy person maintains health (i.e., eats, sleeps, etc.) using the “customary” method; if that person becomes mildly ill, he or she might use the “instrumental” method in deciding what to do (i.e., consciously deciding whether to take a pill, stay in bed, etc.); and if that person should become seriously ill, he or she might use the “command” method by abdicating health decisions to a doctor.

Temin’s model also describes three institutional structures in which decisions are made using the three decision-making methods.¹⁸ A “hierarchy” exists when decision-making entities are arranged in clear power relationships where one entity gives orders and another follows them. A “market” exists when people or firms come together to bargain for mutually-agreeable exchanges. A “community” exists when entities interact “informally or continually on more or less equal footing.”¹⁹

While any of the above modes of behavior can fit into any institutional structure, some fits are uncomfortable. For example, command decision-making fits rather poorly in a community relationship (where customary behavior works much better), and instrumental decision-making fits more comfortably in a market structure than it does in a hierarchy.²⁰ Temin asserts that tensions created when the institutional structure and the decision-making model do not mesh result in pressures to change the institutional structure, not the mode

¹⁸*Id.* at 177-79.

¹⁹*Id.* at 177.

²⁰*Id.* at 180.

of behavior.²¹ So, when personal characteristics combine with unanticipated changes in the outside world to alter the average person's decision-making method, the institutional structure is pushed to transform into a structure more compatible with the behavioral mode.

After articulating his model, Temin uses it to explain the history of congressional and FDA regulation he provides in the rest of the book. For example, Temin states that “the Depression and the war induced a desire for more directed behavior.”²² The increasing pace of drug discoveries (including sulfa drugs in the 1930s and antibiotics after the war) made expert guidance more necessary. Thus, according to Temin, the 1938 FDCA was designed to establish a hierarchic structure to accommodate the growing culture of command-model decision-making.²³ Temin uses his model to explicate other FDA regulatory actions and to try to determine how FDA will react to future changes. In particular, Temin makes an important contribution to the “drug lag” debate by shedding light on the conflicting behavior-model assumptions underlying both sides, and he attempts to use the model to anticipate how FDA – or Congress – will respond to growing pressure (borne of increasingly instrumental consumer behavior with regard to drug selection) to speed drug approval.²⁴

The historical works by Wood, Higgs, and Temin do not adopt the rational actor viewpoint in its purest form. That role is fulfilled best by legislative and regulatory preambles, law casebooks, judicial decisions, or anything else that states the goals of regulation and how the current regulatory scheme achieves those goals, all of which are easy for the researcher to find. While the rational actor model does not preclude disharmony within the government (if it did, it would be uselessly naive), it largely treats such disharmony as peripheral to the main thrust of governmental unity. Wood and Higgs at points both ascribe importance

²¹*Id.* at 179.

²²*Id.* at 198.

²³*Id.* at 199.

²⁴*Id.* at 206-15.

to that disharmony. And while Temin pays relatively less attention to disunity than the others, his model makes FDA regulation as much a product of collective psychological urges than one of rational means-ends reasoning. Nevertheless, these historical works display a greater tendency to view food, drug, and cosmetic regulation as the product of a single-minded government reacting to various influences than the rest of the pieces described in this essay.

III. The Organizational Process Model

Most general theories of agency behavior adopt the organizational process model as their construct. Some political scientists focus on the extent to which Congress is able to control agency behavior,²⁵ while others pay more attention to agency responsiveness to non-governmental pressures.²⁶ Since these theories explain FDA decision-making in terms of FDA's organization-level response to certain incentive structures imposed by various entities, and since they seem applicable regardless of personality changes at FDA, they are included in this classification. Two political scientists in particular – Professors Mary Olson at Yale University and Dan Carpenter at the University of Michigan – are doing fascinating empirical analyses of FDA decision-making at the organizational level.

One of Olson's earliest works, complaining that “few studies have attempted to test among the competing theories of agency behavior,”²⁷ tests for determinants of FDA approval decisions in three different industries: brand-name drugs, generic drugs, and medical devices. The determinants for which she tests include agency

²⁵See generally Barry Weingast & Mark Moran, *Bureaucratic Discretion or Congressional Control: Regulatory Policymaking by the Federal Trade Commission*, 91 J. POL. ECON. 765 (1983) (arguing that agencies are motivated primarily by the preferences of the congressional committees that oversee them because of the rewards and sanctions those committees are capable of dispensing to the agencies); Terry Moe, *Control and Feedback in Economic Regulation: The Case of the NLRB*, 28 AM. J. POL. SCI. 1094 (1985) (arguing that institutional culture and superior expertise make agencies relatively independent from congressional control).

²⁶Perhaps the most important of this branch of theories is the “capture” theory advanced by George Stigler in *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 2 (1971).

²⁷MARY OLSON, REGULATORY AGENCY DISCRETION AMONG COMPETING INDUSTRIES: INSIDE FDA 2 (Center for American Politics and Public Policy Occasional Paper Series No. 94-4, 1994).

budget, congressional preferences, and several measures of both industry interests and consumer interests. Her results suggest that different theories of agency behavior are “correct,” depending on the type of product for which approval is sought.

First, the coefficients on the FDA budget variables in all three approval categories are statistically significant, meaning that the size of FDA’s budget affects how quickly all three regulated articles are approved. Interestingly, the only positive coefficient for FDA’s budget is in the category of generic drug applications; specifically, a one percent increase in agency budget would lead to a 1.01 percent increase in the number of generic drug approvals in any given year.²⁸ Budget constraints will not, therefore, slow the approval rate for brand-name drugs or medical devices. Olson implies that the Pharmaceutical Manufacturers Association may have discovered this relationship earlier, explaining their attempt to limit FDA’s budget (to stifle generic drug approval) after the 1984 Drug Price Competition and Patent Term Restoration Act.²⁹

Olson shows that congressional preferences and the public interest both affect FDA approval speed. Olson uses the ADA³⁰ scores of House and Senate oversight committee members to measure their preferences for more or less restrictive regulations for the three categories of medical technology. The higher the ADA score for the median Senate oversight committee member, the more quickly generic drugs are approved.³¹ The same is true for House committee members and brand-name drug approval. As the median Senate oversight

²⁸*Id.* at 29 tbl.2a.

²⁹*Id.* at 19.

³⁰The group Americans for Democratic Action (“ADA”) issues scores for all congressional members based on roll calls, rating their ideology on a scale from 0 (very conservative) to 100 (very liberal). ADA scores are widely used as a simple proxy for the political preferences of members of Congress.

³¹*Id.* at 29 tbl.2a.

committee member's ADA score increases, medical devices are approved more slowly.³² As for the public interest, the death rate for brand-name drugs directly affects their approval rate, and the pharmaceutical price index affects the approval rate of generic drugs.³³

Olson has also examined determinants of FDA's choice of enforcement tools.³⁴ Her findings demonstrate what common sense would instruct. For example, budget restrictions and increasing applications for product approval both result in less FDA monitoring of regulated industries and the use of "cheaper" enforcement tools in place of more resource-intensive ones.³⁵ Although her findings are not startling, her explanation for them is intriguing and reflects a clear organizational-process orientation. Olson maintains that "changes in FDA enforcement strategies occurred because the *political benefits* of pursuing high monitoring and legalistic enforcement actions diminished over time as firms', consumers', and congressional preferences for more and faster FDA approvals increased."³⁶ The reason for the selection of less expensive enforcement tools, then, is not that FDA simply has less money and more work; rather, FDA changed its primary enforcement tools as a response to signals from Congress³⁷ and from industry that greater political benefits would attach to certain enforcement patterns than to others. Likewise, Olson explains regulatory tightening in response to periodic scandals not as a rational response to a new problem brought to light (as do others mentioned above), but instead as FDA's response to increasing political benefits to stricter enforcement.

³² *Id.*

³³ *Id.*

³⁴ See Mary Olson, *Substitution in Regulatory Agencies: FDA Enforcement Alternatives*, 12 J.L. ECON. & ORG. 376 (1996).

³⁵ *Id.* at 404.

³⁶ *Id.* at 404-05 (emphasis added).

³⁷ "Signals" from Congress are often the most powerful mechanism for political control of an agency. See, e.g., Daniel P. Carpenter, *Adaptive Signal Processing, Hierarchy, and Budgetary Control in Federal Regulation*, 90 AM. POL. SCI. REV. 283 (1996) (arguing, without specific reference to FDA, that presidents and congressmen achieve budgetary control over agencies not by manipulating aggregate resource constraints but by transmitting powerful signals through budget shifts; moreover, bureaucratic hierarchy increases agency response time in processing those signals, limiting efficacy of budget manipulation as a control tool).

The determinants registered different effects on different FDA enforcement tools. For example, the number of FDA inspections dropped as a result of budget cuts, but the number of FDA seizures did not.³⁸ Olson would posit that there must be some reason that a reduction in budget does not constitute a sufficient political incentive for FDA to reduce seizures. More precisely, to understand agency behavior, Olson states that we must understand the internal trade-offs that result in various actions: when FDA's budget is cut, what trade-offs result in a reduction in inspections but not in seizures, or an decrease in generic drug approvals but not in brand-name drug approvals?³⁹

A separate study by Olson concentrates on the relationship between Congress and FDA, and more specifically on Congress' ability to constrain FDA action.⁴⁰ There are two general approaches to congressional control of an agency: ex post monitoring and ex ante administrative or procedural constraints. Olson's study suggests that the ex ante constraints imposed by the 1962 Amendments to the FDCA limit the *direction*, but not the *magnitude*, of agency "drift" from congressional preferences over time.⁴¹ FDA is effectively prevented from becoming more lenient with respect to new drug approval, but its position is not static; FDA decisions exhibit, instead, a policy shift in the direction of increased stringency.⁴² By way of contrast, FDA has fewer legislative constraints on its generic drug approval process, and there has consequently been a greater fluctuation in generic drug approval between leniency and stringency.⁴³ Since there are fewer ex ante constraints imposed by Congress with regard to generic drug approval, FDA is more open to political pressure (which includes ex post congressional oversight) and has more discretion to respond to that pressure.

³⁸*Id.* at 405.

³⁹*Id.*

⁴⁰Mary Olson, *Explaining Regulatory Behavior in FDA: Political Control vs. Agency Discretion*, in 7 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH 71 (Gary Libecap ed., 1996).

⁴¹*Id.* at 73.

⁴²*Id.*

⁴³*Id.*

Institutional culture contributes to the magnitude of FDA's drift toward stringency.⁴⁴ The professional concerns of scientists and doctors result in a preference by FDA for maintaining standards versus increasing speed. As Olson puts it, "an agency staffed with doctors who are bound to the Hippocratic Oath will probably operate very differently than an agency staffed with lawyers or economists."⁴⁵ Since the composition of FDA is predetermined by Congress, and since in drafting FDA's mandate Congress chose to focus solely on safety and efficacy instead of cost effectiveness or other non-scientific concerns, Congress' ex ante control of FDA has given that agency only one direction to move when resources are constrained.

Congress is finding ex post oversight to be a more and more convenient way of maintaining political control over FDA, since any changes in the legislative status quo are practically difficult to bring about and since the informational asymmetry between Congress and FDA is at an all-time high. But congressional oversight tends to be ineffective compared to ex ante control because the worst that can happen to FDA for deviating from congressional preferences is that its budget can be cut.⁴⁶ And as Olson has shown in other works,⁴⁷ such "agency starving" only impacts some kinds of FDA behavior. So, Olson points out, "if politicians want the agency to be more responsive to industry interests, then politicians need to shift the balance of interest reflected in agency process" (ex ante instead of ex post), as they did with the introduction of user fees in 1992.⁴⁸

Some of Professor Olson's more recent research suggests that congressional oversight does have important consequences, regardless of its effectiveness as a mechanism of ex post political control over FDA.⁴⁹ While

⁴⁴*Id.* at 105.

⁴⁵*Id.* at 79.

⁴⁶*See id.* at 102-03.

⁴⁷*See supra* notes 29 and 38 and accompanying text.

⁴⁸Olson, *Explaining Regulatory Behavior in FDA*, *supra* note 40, at 106.

⁴⁹*See* Mary K. Olson, *Agency Rulemaking, Political Influences, Regulation, and Industry Compliance*, 15 J.L. ECON. & ORG. 573 (1999).

it should come as no surprise that heightened FDA inspection activity increases industry compliance with food and drug laws,⁵⁰ expanded congressional oversight of FDA also appears to increase industry compliance. This is for two reasons. First, increased congressional oversight signals to the industry that Congress wants food and drug safety laws to be strictly enforced. The second reason is indirect: greater congressional oversight leads to greater FDA inspection levels. A ten percent increase in oversight hearings results in a two percent increase in FDA inspections.⁵¹ This implies that the reduction in oversight of FDA in the early 1980s contributed to industry non-compliance, and that improved compliance in the late 1980s and early 1990s resulted at least in part from increased congressional oversight of FDA.

Olson wrote one piece that indicates that the characteristics of firms regulated by FDA can serve as signals to FDA about product quality, and that FDA acts on those heuristics.⁵² So, all things being equal, firms with good safety records can get products approved more quickly. Professor Dan Carpenter takes this proposition a step further: even large (and therefore familiar) firms that have historically *below-average* safety records can often get quicker approval than unknown firms.⁵³ This is because, as Carpenter’s formal modeling shows, familiarity advantages are distinct from the firm-specific quality differentials from which FDA learns.

Carpenter demonstrates that large firms receive regulatory “protection” even without being captured by

⁵⁰Specifically, a ten percent increase in aggregate inspections produces a 7.9 percent reduction in the number of firms violating FDA regulations. *See id.* at 589.

⁵¹*Id.* at 593.

⁵²Mary Olson, *Firm Characteristics and the Speed of FDA Approval*, 6 J. ECON. & MGMT. STRATEGY 377 (1997). Olson had also argued that more specialized firms receive quicker approval, but a later work showed that this effect disappeared with the enactment of the Prescription Drug User Fee Act of 1992. *See* Mary Olson, *Regulatory Reform and Bureaucratic Responsiveness to Firms: The Impact of User Fees in FDA*, 9 J. ECON. & MGMT. STRATEGY 363 (2000).

⁵³Daniel P. Carpenter, *Protection Without Capture: Product Approval by a Politically Responsive, Bayesian Regulator* 30 (2000) (working paper, on file with author at the Department of Political Science, University of Michigan).

the industry (that is, even if the regulatory action is for the benefit of consumers and not the regulated industry). There are several reasons why a Bayesian FDA facing a stopping problem⁵⁴ would act to benefit larger, more established firms.⁵⁵ First, larger firms have more products already on the market, so FDA will have less uncertainty about the firm’s ability to make any safe products at all. Second, larger firms have the capital to fill market gaps more quickly, and FDA is likely to respond more quickly to the heightened consumer pressure associated with a breakthrough drug. Finally, larger firms are benefitted indirectly by FDA’s slowness in making stopping decisions. Larger firms have the funds to wait out a long approval process, while small companies may not, effectively protecting large firms from market entry by small ones. Carpenter’s findings cast some doubt on the capture theory of agency behavior, at least as applied to FDA. As Carpenter explains, “commonly adduced evidence for capture and rent-seeking is observationally equivalent to evidence for other models of regulation.”⁵⁶ In other words, while FDA actions that benefit large firms may indicate that FDA has been captured by the firms’ superior money and organization, they may also indicate that FDA is simply a Bayesian regulator facing a stopping problem with incomplete information. Since uncaptured (or “neutral”) agencies can thus unintentionally “bequeath systematic advantages to large firms,” political insulation of an agency may not, as some capture theory adherents claim, create a level playing field for firms of all sizes.⁵⁷

Carpenter focuses more on the central question of the stopping problem – namely, when to decide – in

⁵⁴Political scientists refer to a decision about when to take a costly action that will be costly to undo as a “stopping problem.” FDA faces the problem of “stopping” drug review only when the payoff of approval (including the avoidance of additional political costs of waiting, as with the AIDS drugs in the late 1980s) exceeds both the utility losses (including FDA’s fiercely-guarded reputation) associated with the potential danger of the drug *and the value of waiting for more information*. FDA will not, therefore, simply approve the drug when its apparent danger is less than the apparent payoff of approval, since valuable new information about the drug may be just around the corner. According to Carpenter, it is this aspect of FDA decision-making that differentiates product approval from more standard problems of administrative choice.

⁵⁵*See id.* at 2-3.

⁵⁶*Id.* (from abstract).

⁵⁷*Id.* at 31.

another work.⁵⁸ Indeed, as of the writing of this essay, Carpenter is the only political scientist not to view FDA decision-making as a static choice among several different policy options. This is surprising because, as Carpenter says, “the political debate over FDA drug approval concerns not *whether* the agency rejects or approves too many new drugs, but *how long* it takes for safe and efficacious drugs to get approved.”⁵⁹ Carpenter’s empirical findings are consistent with his speculations in *Protection Without Capture* about why larger firms are disproportionately benefitted by FDA regulation.

In particular, FDA is least likely to approve a drug precisely when Carpenter’s model suggests that the value of waiting for more information is the greatest: when the drug is first submitted.⁶⁰ FDA is not necessarily inefficient, then, even if it is slow; its decisions simply account for the value of waiting. Second, FDA review times seem to be shortest when it is reviewing the first drug submitted for a particular disease, since political demand (generated by organized consumer groups and media coverage of a disease) for the drug is strongest when no alternative exists.⁶¹ The payoff for early approval is greater, the costs of waiting are lower, and the benefits of waiting are the same relative to later drugs.

Carpenter has also researched what influences the waiting costs that FDA takes into consideration when deciding when to decide.⁶² He demonstrates that “political influence in FDA drug approval occurs less through ideological and partisan shifts in the agency’s oversight institutions (the presidency, Congress and its committees), and more through organized interests.”⁶³ Indeed, oversight committee ideology and parti-

⁵⁸Daniel P. Carpenter, *Bureaucratic Choice as a Stopping Problem: A Theoretical and Empirical Analysis of FDA Drug Review* (April 1999) (paper prepared for the Midwest Political Science Association Meetings) (on file with author).

⁵⁹*Id.* at 2 (emphasis in original).

⁶⁰*Id.* at 35.

⁶¹*Id.* at 5.

⁶²Daniel P. Carpenter, *Groups, the Media, and Agency Waiting Costs: The Political Economy of FDA Drug Approval* (April 2000) (paper prepared for the Midwest Political Science Association Meetings) (on file with author).

⁶³*Id.* at 2.

sanship are not correlated to a statistically significant degree with FDA review times.⁶⁴ On the other hand, increased media coverage of a particular disease (as measured by the four-year moving average of *Washington Post* stories mentioning the disease) is highly correlated with reduced approval time for a drug relating to that disease.⁶⁵ Finally, disease-specific activists can increase FDA's political waiting costs. But it is the centralization, and not the number, of such groups that counts; one group with substantial wealth is more effective than many groups with fewer resources.⁶⁶ In sum, influences on FDA's waiting costs seem to be disease-specific and not systematic.

As of the writing of this essay, Professor Carpenter, along with Professor Michael Ting, is in the process of formalizing an additional dimension to his model of FDA's stopping problem.⁶⁷

Comment 2. Pooling Equilibrium. (i) If $p_1 \notin (\frac{k_r}{f(\theta_1)}, 1 + \frac{k_r}{f(\theta_2)})$, then an equilibrium exists where $\sigma^*(\theta) = 0 \forall \theta$, $\mu(1) = 0$, $\mu(0) = p_1$, $\rho^*(s) = 0 \forall s$, $\alpha^*(1, \emptyset) = 1$, and $\alpha^*(0, \emptyset) = 1(0)$ for $p_1 > (<) \frac{-f(\theta_2)}{f(\theta_1) - f(\theta_2)}$.

Daniel Carpenter & Michael M. Ting, Product Approval with Endogenous Submissions (October 25, 2000) (working paper, on file with author). It should be noted that formal modeling of the type done here is not for the faint of heart. For example, "comments" such as these are typical:

⁶⁴*Id.* at 19-20. Carpenter's results on ideology and partisanship are fascinating. Although the results are statistically insignificant, a more liberal House oversight committee and a majority-Democrat Senate are both associated with *quicker* approvals. On the other hand, perhaps more in line with expectations, approvals are slower under a more liberal Senate oversight committee, a Democrat-controlled House, and Democratic presidents.

⁶⁵*Id.* at 21. This confirms the speculations of journalists and historians. See, e.g., HERBERT BURKHOLZ, FDA FOLLIES 113 (1994).

⁶⁶*Id.* at 24.

⁶⁷

Researchers who plan to empirically test this new model, or other of Carpenter’s or Olson’s models with new data, should therefore have a solid background in at least propositional and predicate calculus. Specifically, Carpenter and Ting are studying the strategic interaction between FDA and firms submitting drug applications to FDA. This is important because a complete model of FDA decision-making requires an understanding of how firms will react to FDA’s decision-making strategy, and how FDA will react to their reaction, and so on.

According to the model, once a firm has a product it thinks will be profitable, the firm must choose how much of a delay (and, therefore, how much more testing) to impose on itself before seeking FDA approval. The firm does not begin the process of deciding whether to submit or delay, under this model, until it is satisfied with its own knowledge of how safe and effective the product is. Once FDA approval is sought, the model assumes the firm’s knowledge of its own product’s safety/efficacy level. FDA must then decide how much additional delay and testing is needed before “stopping” the process and approving or rejecting the submission. Self-delaying is costly for a firm, but the longer it delays (and the more testing it does), the less likely FDA is to impose additional delay and investigation costs on the firm, and the more likely FDA is to rely on the firm’s signals (true or false) about the quality of its product. Ultimately, FDA would like to know what the firm knows – the product’s true safety/efficacy level – but acquiring such knowledge is very costly for FDA. This balancing act is what Carpenter and Ting formalize in their model.

As implied above, Carpenter and Ting’s model assumes that there are at least some products that firms would like to sell but that FDA would not approve. If the interests of the two parties were coextensive, there would be no need for a firm to try to “convince” FDA that its product is safe and effective; the two would simply collaborate to discover the truth. In this respect, Carpenter and Ting’s model is comparable to regulatory models advanced by other scholars. For example, an agency may overestimate its budgetary needs to Congress to get more money, but if it overestimates too much, it risks being audited and getting even less money.⁶⁸ The agency finds equilibrium – and makes its decision – at the point where the risk of being audited with a higher estimate outweighs the possible benefit of getting more money. Likewise, the firm submitting an application to FDA decides to submit at the very point when the costs imposed by any additional delay outweigh the possible additional benefits of signaling to FDA that sufficient testing has been done. FDA decides when to decide based, in part, on those signals.

A useful non-empirical examination of FDA’s decision-making incentives from an organizational approach is

⁶⁸ See Jeffrey S. Banks, *Agency Budgets, Cost Information, and Auditing*, 33 AM. J. POL. SCI. 670 (1989).

David Leo Weimer’s *Organizational Incentives: Safe – and Available – Drugs*.⁶⁹ While FDA might ideally outlaw only products that no fully-informed person would use, FDA has perfect information about neither the products nor the preferences or benefit-risk ratios of all the sub-populations of people it protects.⁷⁰ Given this lack of information, all FDA decisions must weigh in general terms the costs of keeping a product off the market against the benefits and risks of letting it on the market. Since FDA suffers much greater political punishment for letting a dangerous product on the market than for keeping a useful one off, the equation is tilted toward conservatism.⁷¹ Much of the rest of Weimer’s chapter explains in greater detail the incentives underlying FDA’s conservatism, the costs of FDA’s inflexibility, and possible solutions to the problem.

IV. The Bureaucratic Politics Model

This section will introduce the small number of works that pay special attention to the individuals who come together to cause a particular outcome, instead of to organizational or governmental incentives and rationality. This section will also briefly describe one more study by Professor Olson which, although it does not describe FDA decision-making per se, empirically analyzes the individual-level politics involved in the passage of the 1984 Drug Price Competition Act (“DPCA”) and the Patent Term Restoration Act (“PTRA”). It is a useful piece for any researcher interested in the politics of pharmaceutical regulation in general and not specifically in FDA.

Herbert Kaufman’s *The Administrative Behavior of Federal Bureau Chiefs*⁷² asserts the importance of federal bureau chiefs in bureaucratic decision-making, and he incorporates six specific leadership positions into

⁶⁹ *In* REFORMING SOCIAL REGULATION: ALTERNATIVE PUBLIC POLICY STRATEGIES 19 (LeRoy Graymer & Frederick Thompson eds., 1982).

⁷⁰ *See id.* at 36-39.

⁷¹ *See, e.g., id.* at 21.

⁷² HERBERT KAUFMAN, *THE ADMINISTRATIVE BEHAVIOR OF FEDERAL BUREAU CHIEFS* (1981). Another valuable, but considerably older, account of the power of bureau chiefs is ARTHUR W. MACMAHON & JOHN D. MILLETT, *FEDERAL ADMINISTRATORS: A BIOGRAPHICAL APPROACH TO THE PROBLEM OF DEPARTMENTAL MANAGEMENT* (1939).

his study (FDA commissioner among them). Beyond making the concededly easy argument that bureau chiefs are important, though, Kaufman undertakes to describe how they run their agencies. Kaufman discusses how bureau chiefs acquire, evaluate, and use information, how they handle other governmental actors, how and when they delegate tasks, how and when they develop routines, how they shape the current and future operations of their agencies, and what personality qualities bureau chiefs need to succeed. There is no chapter devoted specifically to FDA, but examples of FDA commissioners' actions are woven throughout the book to illustrate the propositions Kaufman advances about bureau chiefs in general or to carve out exceptions to those propositions.⁷³

The importance of the particular FDA commissioner to FDA decision-making is emphasized in a study by B. Dan Wood and Richard W. Waterman.⁷⁴ Wood and Waterman examined the tenure of Arthur Hayes as FDA's commissioner. Hayes was appointed in April 1981 by Health and Human Services ("HHS") Secretary Richard Schweiker as part of an effort by President Reagan's Task Force on Regulatory Relief to speed up the new drug approval process. As expected, FDA approved more new drugs in 1981 than it had in any year since the 1962 Amendments.⁷⁵ But while there was strong political support for reducing drug approval time and cost, there was no evidence of any political support for slackening FDA's enforcement functions.⁷⁶ Wood and Waterman examine whether Hayes brought such a slackening about, regardless of the lack of an executive mandate to do so.

⁷³See, e.g., *id.* at 162-63. For example, one such proposition is that bureau chiefs generally desire more power and autonomy. But that is not always the case. As Kaufman explains, FDA Commissioner Donald Kennedy opposed the recommendation of the National Academy of Sciences to give FDA discretion to calculate the costs and benefits of various food additives and to devise an appropriate strategy for each additive. Otherwise, the FDA commissioner would be the target of political pressure on all sides of debates on each additive.

⁷⁴B. DAN WOOD & RICHARD W. WATERMAN, *supra* note 8, at 27-76. The study was first published in B. Dan Wood & Richard W. Waterman, *The Dynamics of Political Control of the Bureaucracy*, 85 AM. POL. SCI. REV. 801 (1991).

⁷⁵See *id.* at 55.

⁷⁶See *id.*

Despite a gradual increase in FDA's budget throughout the early 1980s, food and drug establishment inspections declined consistently until they reached 60.22 percent below the pre-Hayes level.⁷⁷ Product seizures declined 43.9 percent in the first quarter Hayes served as FDA commissioner and remained at that level throughout the 1980s; legal actions (defined here as the sum of all prosecutions and injunctions obtained by FDA) declined by 49.6 percent in the same quarter and also remained at that level.⁷⁸ Given these data, Wood and Waterman "posit a straightforward case of top agency leadership manipulating the activities of an agency."⁷⁹ Wood and Waterman empirically establish what Kaufman deduces by observation: the person in the FDA commissioner's, or HHS secretary's, seat is an important determinant of how FDA behaves. Rita Campbell's *Drug Lag*⁸⁰ is perhaps the clearest example of a political science analysis of FDA using the bureaucratic politics framework. *Drug Lag* is not a comprehensive study of FDA decision-making. Instead, it is an account of how the various personalities inside FDA (and personalities outside FDA that had an impact on FDA) reacted to the "drug lag" debate, written by one of the founding members of the National Advisory Drug Committee. Any researcher wishing to examine a microcosm of FDA decision-making from the bureaucratic politics or psychological point of view should not miss this book.

Finally, part of Mary Olson's Ph.D. dissertation,⁸¹ and a later article⁸² building on it, study why regulatory reform proposals prior to the 1984 DPCA and PTRAs were stalled, and why the 1984 legislation was actually

⁷⁷*Id.* at 56.

⁷⁸*Id.* at 57.

⁷⁹*Id.* at 55.

⁸⁰RITA RICARDO CAMPBELL, *DRUG LAG: FEDERAL GOVERNMENT DECISION MAKING* (1976)

⁸¹Mary K. Olson, *The Effects of Drug Regulation and the Scope for Political Influence* (1991) (unpublished Ph.D. dissertation, Stanford University) (on file with University Microfilms International).

⁸²Mary K. Olson, *Political Influence and Regulatory Policy: The 1984 Drug Legislation*, 32 *ECON. INQUIRY* 363 (1994).

enacted. Olson’s results demonstrate that the political preferences (represented by ADA scores and campaign contributions) of key congressional committee⁸³ members favored the status quo over any proposed bills before 1984, and that changes in House committee and subcommittee membership combined with a change in party control of the Senate to create a mix of political preferences that instead favored reform over the status quo. Olson explains that “as membership and preferences on these committees change over time, the set of policies which can be supported by a majority on the committee will also change.”⁸⁴ Olson’s results also show that, while the wishes of a subcommittee chair (particularly, in this case, Henry Waxman) can be stymied by the other subcommittee members, the chair (in addition to being able to prevent bills from reaching the floor) can influence the composition of the subcommittee over time, bringing the subcommittee more in line with his or her preferences.

V. Miscellaneous Works

Three political science pieces would fit so awkwardly into any one of the three models that to force them to do so would be more misleading than helpful. These works explore the operations of FDA using more than one framework, and would be useful references no matter what lens the future researcher uses to examine FDA.

Paul Quirk’s chapter on FDA in James Q. Wilson’s *The Politics of Regulation*⁸⁵ is perhaps the single most indispensable political science piece on FDA, and certainly one of the most cited. In this chapter, Quirk analyzes the politics of drug legislation in 1906, 1938, and 1962, claiming that the enactment of these laws

⁸³Particularly the House Subcommittee on Health and the Environment, of which Henry Waxman was chair, and the Senate Committee on Labor and Human Resources, of which Orrin Hatch was chair.

⁸⁴*Id.* at 381.

⁸⁵Paul J. Quirk, *Food and Drug Administration*, in *THE POLITICS OF REGULATION* 191 (James Q. Wilson ed., 1980).

depended on the overall political climate and was not necessarily intended to benefit the industry, even though the industry supported it.⁸⁶ Quirk's telling of the history of drug legislation is notable in that it is centered on politics and not on policy; individuals are vital to Quirk's account. Despite the politics orientation, however, Quirk includes discussion of the policy dilemmas inherent in drug regulation.

Quirk reviews internal (especially personnel) factors that account for FDA behavior. For example, Quirk explains that since FDA medical officers "do little creative research; instead, they evaluate research submitted by drug companies," FDA often has trouble recruiting top minds.⁸⁷ Salary and working conditions at FDA are also not comparable to what physicians can get in private practice. Managerial problems plagued the Bureau of Drugs in the late 1960s and early 1970s, and internal conflict has hindered FDA's drug approval policy.⁸⁸ If FDA is slow or inefficient, then, it is partly because of the people there and not because of the agency's incentives or the laws governing FDA.

Quirk also discusses in some detail several external factors that influence FDA decision-making, such as industry lobbying, consumer groups, public opinion, and congressional oversight. Quirk even tells one tale (calling it the "exception that proves the rule") of attempted political intervention on behalf of a drug: when FDA declared the combination antibiotic Panalba ineffective, the Upjohn Company convinced HEW Secretary Robert Finch to order FDA to grant Upjohn a hearing, but Finch's order was quickly reversed by the House Committee on Government Operations.⁸⁹ Presaging the Wood and Waterman study, Quirk also points to presidential influence through high-level FDA appointments.⁹⁰ Finally, Quirk remarks that the balance of all these external influences "fluctuates with events, with the rise and decline of social movements

⁸⁶*Id.* at 201.

⁸⁷*Id.* at 207.

⁸⁸*Id.* at 207-08.

⁸⁹*Id.* at 212.

⁹⁰*Id.* at 217.

and political organizations, with experience of the impact of previous regulatory decisions, and with broad changes of public attitude.”⁹¹

Stephen Ceccoli’s Ph.D. dissertation⁹² offers a fascinating comparative political science approach to drug regulation in the United States. Much of the dissertation adopts a rational actor view of American drug regulation. Chapter 2, for example, is aimed at showing that the differences between American and British political institutions themselves explain variation in the political responsiveness of the drug regulatory agencies as well as in the attitudes of regulatory officials. Nevertheless, an organizational process framework is evident in Ceccoli’s discussion of FDA’s recent shift away from its single-minded protection of the consumer to its dual role of consumer protection and promotion of new medical treatments through quick drug approval; FDA’s “regulatory shift” was due to pressures from the anti-regulatory Reagan and Bush administrations, consumer groups (particularly AIDS groups), and the pharmaceutical industry.⁹³ Making the categorization of this work particularly difficult is that Ceccoli consistently uses four factors in his analysis of regulatory behavior: history and path dependence (the effect of the past and of routine on current practice), the degree of goal consensus or controversy (i.e., the clarity of the legislative mandate), the level of political support the agency gets, and nature of the relationship between the regulated industries and the agency. For the future researcher, Ceccoli’s dissertation also contains an excellent bibliography of government documents related to the study of FDA.

A general work that serves as a good introduction to theories of regulatory politics in general and to FDA behavior in particular is Sidney Shapiro and Joseph Tomain’s *Regulatory Law and Policy*.⁹⁴ It is structured

⁹¹*Id.* at 218.

⁹²Stephen J. Ceccoli, *The Politics of New Drug Approvals in the United States and Great Britain* (1998) (unpublished Ph.D. dissertation, Washington University) (on file with the Harvard Law School Library).

⁹³*Id.* at 248-57.

⁹⁴SIDNEY A. SHAPIRO & JOSEPH P. TOMAIN, *REGULATORY LAW AND POLICY* (1998).

like a casebook in that it contains excerpts from other sources followed by notes and questions. Chapter 3, “Regulation and Politics,” provides a strong theoretical anchor for political science research on agency decision-making. Chapter 11 contains a case study of FDA, including history, policy justifications for current drug law, and passages from scholarly debates on whether FDA should allow very ill people to access drugs even if FDA has not approved them. The notes and questions to the case study provide a good discussion of the policy debates involved in new drug approval.

VI. Conclusion

The current state of the political science literature on FDA is easy to describe because it has few internal conflicts. Not surprisingly, FDA decision-making is influenced by a number of factors, including congressional preferences (as manifested by, among other things, oversight activity and budget manipulation), presidential preferences, personalities in FDA, agency incentives, and, in some circumstances, FDA’s budget itself. The weight of various factors depends on which industry is being affected and what type of decision – i.e., when a decision is made or what the decision itself was – is being examined. The real use of a political science analysis of FDA is in understanding which factors tend to matter most in a particular situation, and how they will bring their influence to bear, and why. The ultimate goal is the ability to predict what will happen given a specific set of circumstances; that is why political science has even the smallest of claims to the term “science.”⁹⁵

As should be clear from this essay, the political science literature on FDA exhibits a great variety. Nevertheless, it has notable gaps. First, nearly all of the empirical work and the vast majority of the work in general focuses primarily on drug regulation. The field would benefit tremendously from a study of FDA

⁹⁵The inability to make consistently *accurate* predictions does not undermine the pursuit’s status as a science; astrophysics has historically had this problem, and meteorology still does.

decision-making regarding other FDA-regulated industries such as food, cosmetics, or animal feed. Second, while political science works using the rational actor model or the organizational process model are relatively easy to come by, fewer FDA-specific works adopt the bureaucratic politics model, and even fewer examine FDA politics at the individual level beyond the post of FDA commissioner. This is, at least in part, due to the informational problems associated with describing the decision-making process using that framework: not only must such a description be intensely fact-specific and therefore limited both in scope and in broader application, but the relevant facts are also very difficult to discover for anyone but FDA insiders. While the organizational process model might be the most convenient analytical lens through which to examine FDA, the study of FDA decision-making could use more carefully researched, individual-level accounts of important FDA decisions.

The future researcher can take some comfort in the bibliographical completeness of this essay as of the time it was written, but he or she should remember that it is “complete” only to the extent that it covers the limited category of political science research (defined narrowly) specifically on FDA. There are numerous political science works on health care regulation or on the bureaucracy in general, and there are literally thousands of books and articles not mentioned here that touch on some aspect of FDA. Economics, history, law, psychology, biochemistry, and other disciplines can, of course, contribute to the study of how FDA decides “who gets what, when, and how,” or of “how goals [are] determined, conflict resolved or managed, standards set, and policy enforced.”⁹⁶ While there is – and ought to be – a porous barrier between disciplines that examine a common target, some segregation, however debatable the dividing line, is necessary lest any survey span the entire web of human knowledge.

⁹⁶Wilson, *supra* note 85, at xi.